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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/270,437	03/16/1999	YAO-TSENG CHEN	LUD5538.1CIP	2508
24972	7590	02/26/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			CANELLA, KAREN A	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/270,437	<b>Applicant(s)</b> CHEN ET AL.	
	<b>Examiner</b> Karen A Canella	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 110-124, 128, 131-133, 135-140, 142 and 145-151 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 110-117, 124, 132, 133, 135-140, 148-150 is/are allowed.
- 6) ☐ Claim(s) 118-123, 128, 131, 145-147 and 151 is/are rejected.
- 7) ☐ Claim(s) 142 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

Claims 112-124, 128, 145-147, 150 and 151 have been amended. Claims 125 and 127 have been canceled. Claims 110-124, 128, 131-133, 135-140, 142 and 145-151 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim 131 is objected to for the typographical error of "comparing" rather than "comprising". appropriate correction is required.

Claim 142 is objected to under 37 CFR 1.75 as being a duplicate of claim 140..

Claim 131 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how a separate portion of each of (i), (ii) and (iii) is to be determined; whether this "separate portion" refers to a portion of the nucleotide sequences or if "separate portion" refers to the physical containment within the kit. In the event that the physical containment within the kit is applicant intention with respect to the wording "separate portion" , it is noted that claim 131 would have the same scope as claim 149 and would therefore be a duplicate claim.

Claim 151 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

The claim has been amended to recite a composition comprising a plurality of expression vectors in place of an expression vector encoding a plurality of peptides. Neither the specification nor the originally filed claims provide support for this amendment . Applicant is

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invited to point out page and line numbers of the specification in order to overcome this rejection.

The rejection of claims 112-117 and 124 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated vectors and isolated host cells comprising said vectors, does not reasonably provide enablement for vectors and host cells comprised within an animal or human being having been treated by gene therapy is withdrawn in light of applicants amendments.

The rejection of claims 118-123, 128 and 145-147 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 118-121 are drawn to the recombinant cells of claims 114-117, respectively, wherein the recombinant cell further comprises an expression vector which contains a nucleic acid molecule encoding a cytokine which is operable linked to a promoter. Claim 128 is drawn to an expression system useful in making a recombinant cell, comprising a first vector which encodes the protein encoded by the isolated nucleic acid molecules of claim 110 or 111, and a second vector which either encodes an MHC or an HLA molecule or an interleukin. Claim 145 is drawn to a composition useful in treating a subject afflicted with cancer comprising the recombinant cell of claim 125 and a pharmaceutically acceptable adjuvant. Claim 146 embodies the composition of claim 145 wherein said recombinant cell expressed an HLA or MHC molecule. Claim 147 embodied the composition of claim 145 wherein said recombinant cell is a human cell. For the reasons stated above, the specification is not enabling for the use of the disclosed expression vectors and host cells for nucleic acid based therapies, wherein the expression vectors or host cell comprising said expression vectors are administered to patients having a therapeutic need for the protein expressed thereby. The specification teaches that the SEQ ID NO:5 and 7 are shorter and longer versions, respectively, of the KOC-2 gene and SEQ ID NO:6 and 8 are shorter and longer versions of the KOC-3 gene (page 12, lines 4-18). The specification teaches that both KOC-2

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and KOC-3 are overexpressed in melanoma cells (page 14, lines 5-11). The specification is enabling for the isolated nucleic acids encoding KOC-2 and KOC-3 for use in diagnostic assays and expression vectors and host cells for obtaining recombinant protein for making antibodies for use in diagnostic assays. However, the specification does not contemplate a use for vectors, expression systems or host cells comprising the KOC isolated nucleic acids in combination with nucleic acids encoding cytokines, interleukins, MHC or HLA molecules, which would not be part of a therapeutic nucleic acid therapy. Thus, for the reasons set forth above, without further guidance from the specification, one of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to practice the claimed invention.

Applicant has amended the claims to recite "isolated expression vector"; however, the rejected claims 118-123 and 128 have the limitation of an expression vector which contains a nucleic acid molecule encoding a cytokine or an interleukin, or a vector which encodes an MHC or HLA molecule; rejected claims 145-147 have the limitation of including an adjuvant. The specification does not provide an enablement for said isolated expression vectors and compositions comprising isolated recombinant cells comprising an adjuvant that would not be directed to the administration of said expression vectors and cells in vivo. The specification does not contemplate a use for vectors, expression systems or host cells comprising the KOC isolated nucleic acids in combination with nucleic acids encoding cytokines, interleukins, MHC or HLA molecules, which would not be part of a therapeutic nucleic acid therapy.

The rejection of Claims 112-124, 128 and 145-147 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in light of applicant amendments.

The rejection of claims 150 and 151 under 35 U.S.C. 102(e) as being anticipated by Ross (US 6,255,055, priority to March 9, 1998) is withdrawn in light of applicants amendments.

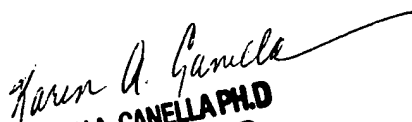
All other rejections and objections as set forth in the previous Office action are withdrawn.

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Acknowledgement is made of applicants complaint about the response of the Office to a filed amendment. Applicant is invited to petition for a re-setting of applicants time. The examiner is not authorized to perform such adjustments of patent term.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (571) 272-0828. The examiner can normally be reached on Monday through Friday from 9 am to 6:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at 703-308-4357.

  
**KAREN A. CANELLA PH.D.**  
**PRIMARY EXAMINER**

Karen A. Canella, Ph.D.

Primary Examiner, Group 1642

02/22/04